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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,595

04/27/2006

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EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,595	Applicant(s) SACKTOR ET AL.	
	Examiner STACEY MACFARLANE	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 14-16, 18-22 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 12, 14-16, 18-21 and 24-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 9, 2009 has been entered.

Response to Amendment

2. Claim 22 has been amended and Claim 38 is newly added as requested in the amendment filed on April 9, 2009. Following the amendment, claims 1-9, 12, 14-16, 18-22 and 24-38 are pending in the instant application.

Claims 1-9, 12, 14-16, 18-21 and 24-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on 2/25/2008.

Applicant should note that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 22 and 38 are under examination in the instant office action.

3. Applicant's arguments filed on April 9, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. As currently amended, Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record in the previous Office action mailed April 11, 2008.

6. The claim is drawn to a purified antibody which specifically binds to the atypical isoform protein kinase M zeta. Examiner maintains that the claim encompasses a genus of antibodies and that the recitation of “the atypical isoform” within the claim does not distinguish the specific antigen to which the antibody binds.

7. In Remarks filed April 9, 2009, Applicant states, “This amendment overcomes the rejection by specifically reciting the antigen to which the antibody binds. Paragraphs 179-203 of the present application ... reasonably convey to one skilled in the relevant art that the Applicant had possession of the claimed invention.” (page 9). While this has been carefully considered it is not found persuasive to overcome the rejection for the following reasons.

8. As amended, the recitation of “the atypical isoform” of PKM ζ within the claim does not distinguish the antigen to which the antibody binds because there is no explicit description for “the atypical isoform” of PKM ζ . Paragraph 179 of the application describes the antibody of the claim as raised against peptides that “corresponded to the

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amino-terminal (ζ N1, TDPKMDRSGGRVRLKC, SEQ ID NO: 1), catalytic-domain (ζ -C2, TLPPFQPQITDDYGLC, SEQ ID NO: 2) or carboxyl-terminal (ζ -C1, EYINPLLLSAEESV, SEQ ID NO: 3) of PKC ζ .” The disclosure states that the ζ -C1 “detects both atypical forms” (paragraph 0185) but the claim encompasses the genus of antibodies and does not distinguish between the species raised against different antigens.

9. A recent decision the Board upheld the written description rejection for an antibody on the basis that the antigen was not adequately described (Ex parte Alonso, No. 2006-2148 (B.P.A.I. July 25, 2007)). Alonso’s claim is drawn to “a monoclonal antibody idiotype to the neurofibrosarcoma of said human.” The Board states, “The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method”. As is the case here, the specification has not adequately described the genus of antibodies encompassed by the claim. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 22 stands as rejected under 35 U.S.C. 102(b) as being anticipated by Naik (2000), for reasons of record in the previous Office action.

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12. On page 10 of Remarks filed April 9, 2009, Applicant traverses the rejection on the grounds:

Naik discloses two non-specific PKC antisera being added at different concentrations to rat hippocampus tissue. See Page 245 left column third full paragraph of Naik. The antiserum disclosed in Naik is to the C-terminus of PKM ζ , which, however, because the sequence is almost entirely shared with PKC ι , is not specific to ζ and does not distinguish between ζ and ι . See Page 244 right column first full paragraph of Naik. The antibody recited in claim 22 is specific to PKM ζ because it is to a sequence found in ζ but not ι , and therefore does not cross-react with PKC ι . Thus, Naik is a deficient anticipatory reference for at least the fact that it does not disclose a purified antibody which specifically binds to the atypical isoform PKM ζ , which is recited in Claim 22 of the present application.

While this argument has been fully considered it is not found persuasive for the following reasons.

Examiner maintains that the Naik prior art teaches a purified antiserum that specifically binds to PKM ζ . The claim does not require that the antibody bind to a specific antigen that is exclusive to PKM ζ . As stated above in sections 8 and 9 of the instant Office action, because the claim fails to adequately describe the antigen to which the antibody binds, the invention encompasses a genus of antibodies. Contrary to Applicant's assertions, the antibody recited in claim 22 is not specifically drawn to a sequence found in ζ but not ι . Thus, the genus of antibodies includes those antibodies that cross-react with PKC ι . Therefore, the antibody of the instant claims fails to distinguish over that of the prior art and the rejection on the grounds of anticipation is maintained.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. As amended Claims 22 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hrabetova et al., Journal of Neuroscience, 16(17):5324-5333, September 1, 1996.

14. Claim 22 is drawn to a purified antibody which specifically binds to the atypical isoform protein kinase M zeta (PKM ζ). Claim 38 is drawn to a purified antibody which specifically binds to the atypical isoform protein kinase C δ/λ (PKC δ/λ).

15. The Hrabetova et al. prior art teaches C-terminal antisera that are specific to isozyme type, and which specifically binds to isoform PKM ζ (Fig 4C, for example). Furthermore, the reference specifically distinguishes an antiserum raised against the catalytic domain of δ/λ (page 5325, column 1, last full paragraph). Therefore, the antibodies of the instant claims fail to distinguish over those of the prior art.

Conclusion

16. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and ALT F 5:30 to 3:30, TELEWORK-Thursdays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649